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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/627,114	07/25/2003	Peter Paul Zilla	P-8794.05 Continuation 2	3869

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EXAMINER	
WILLSE, DAVID H	

ART UNIT	PAPER NUMBER
3738	

MAIL DATE	DELIVERY MODE
05/18/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/627,114	ZILLA ET AL.	
	Examiner	Art Unit	
	Dave Willse	3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 November 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *71-87* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *71-87* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 71, 72, 74, 76, 78, 79, and 82-84 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by Alt, US 2004/0039438 A1. The scaffold **32** includes interconnected pores bordered by microspheres bonded to one another; said pores are defined by surfaces that are spherically concave (Figure 2; paragraph **0033**; etc.) and thus uniformly shaped. The ingrowth matrix generally involves drugs incorporated in a biodegradable carrier (e.g., paragraph **0041**) and comprises a concentration gradient by virtue of the larger reservoir or repository toward the base layer **30** (paragraphs **0011**, **0034**, and **0040**). Regarding claims 74, 76, 78, and 79, viruses and genes (abstract, last sentence; paragraphs **0042** and **0044**) inherently possess proteins and peptides. Regarding claim 82, the stent may take on a helical form (paragraphs **0021** and **0030**), wherein the interconnecting channels would collectively be helically oriented. Regarding claim 83: paragraph **0031**. Regarding claim 84, the term "spherical" means "[o]f or pertaining to a

sphere" (*Webster's II New Riverside University Dictionary*, 1984); the pore shapes pertain to a sphere in that they are defined by adjacent microspheres.

Claims 73, 75, 77, 80, 81, and 85-87 are rejected under 35 U.S.C. 103(a) as being unpatentable over Alt, US 2004/0039438 A1. Regarding claim 73, hydrogels were well known in the art at the time of the present invention and would have been obvious in order to contain medicaments in solution. Regarding claims 75, 77, and 80, materials such as collagen and growth factor would have been obvious in order to facilitate endothelial cell growth and/or gene transfer. Regarding claim 81, polyethylene glycol was well known as a base for pharmaceuticals and would thus have been obvious to the ordinary practitioner for carrying certain types of drugs. Regarding claims 85-87, stents are commonly used for affixing vascular grafts and heart valves (including sewing rings) within the circulatory system; to incorporate the Alt coating system into such stents would have been obvious in order to provide drug delivery when indicated.

The Applicant's remarks have been considered. The Applicant argues that "it would be clear to one of skill in the art that merely changing the ***size*** of a reservoir or repository, and correspondingly changing the ***volume of material*** with which it is filled, does not change the ***concentration*** of the material within the reservoir or repository" (Applicant's reply of February 27, 2007: page 4, lines 15-18; emphasis in original). The word "concentration" is defined as "the amount of a component in a given area or volume" (*Merriam Webster's Collegiate Dictionary*, 10th ed.: 1996). In present claim 71, line 4, the "material" as claimed may be interpreted as the material of the matrix itself or as a second material in the form of a drug or the like. Because of the larger reservoir or repository toward the base layer **30** in the Alt device, there exists a greater amount of matrix material (or biodegradable carrier) and a greater amount of drug in overall unit

volumes (including volume occupied by microspheres) nearer to the base layer. The term "concentration gradient" is not defined in a manner prescribed by MPEP § 2111.01; the examiner must give the present claims their broadest reasonable interpretation (MPEP § 2111). Moreover, once implanted, continuing *diffusion* of the carrier from inner portions of the scaffold **32** to outer portions (paragraph **0041**, last sentence) necessitates concentration gradients of the carrier and hence the drug. Regarding claim 84, the shapes of the spaces between the spherical particles in the Alt implant are primarily defined by portions of spherical surfaces; said shapes thus "pertain" to a sphere.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a). A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dave Willse, whose telephone number is 571-272-4762 and who is generally available Monday through Thursday and often on Friday. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott, can be reached on 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Dave Willse
Primary Examiner
Art Unit 3738